



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Mallinckrodt, LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on February 19, 2016, Mallinckrodt, LLC, 3600 North Second Street, Saint. Louis, Missouri 63147 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Gamma Hydroxybutyric Acid (2010)	I
Tetrahydrocannabinols (7370)	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Norlevorphanol (9634)	I
Acetyl Fentanyl (N-(1-phenethylpiperidin -4-yl)-N-phenylacetamide) (9821)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Nabilone (7379)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II

Controlled Substance	Schedule
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacturer bulk active pharmaceutical ingredients (APIs) for distribution to its customers.

Dated: May 16, 2016.

Louis J. Milione,
Deputy Assistant Administrator.